# House File 2384 - Introduced

HOUSE FILE 2384
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 607)

## A BILL FOR

- 1 An Act relating to the medical cannabidiol Act, making
- 2 related modifications, and providing for civil and criminal
- 3 penalties and fees.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 124D.2, Code 2016, is amended by striking
- 2 the section and inserting in lieu thereof the following:
- 3 124D.2 Definitions.
- 4 As used in this chapter:
- 5 1. "Cannabidio1" means a nonpsychoactive cannabinoid found
- 6 in the plant Cannabis sativa L. or Cannabis indica or any
- 7 other preparation thereof that is essentially free from plant
- 8 material, and has a tetrahydrocannabinol level of no more than
- 9 three percent.
- 10 2. "Debilitating medical condition" means any of the
- 11 following:
- 12 a. Intractable epilepsy.
- 13 b. Multiple sclerosis.
- 14 c. Cancer, if a health care practitioner has determined a
- 15 prognosis for a patient of less than twelve months of life.
- 16 3. "Department" means the department of public health.
- 17 4. "Health care practitioner" means an individual licensed
- 18 under chapter 148 to practice medicine and surgery or
- 19 osteopathic medicine and surgery who provides specialty care
- 20 for a resident of this state for one or more debilitating
- 21 medical conditions.
- 22 5. "Intractable epilepsy" means an epileptic seizure
- 23 disorder for which standard medical treatment does not prevent
- 24 or significantly ameliorate recurring, uncontrolled seizures or
- 25 for which standard medical treatment results in harmful side
- 26 effects.
- 27 6. "Medical cannabidiol manufacturer" means an entity
- 28 located in this state and licensed by the department to
- 29 manufacture and to possess, cultivate, harvest, package,
- 30 process, transport, supply, and dispense cannabidiol pursuant
- 31 to the provisions of this chapter.
- 32 7. "Primary caregiver" means a person, at least eighteen
- 33 years of age, who has been designated by a patient's health
- 34 care practitioner or by a person having custody of a patient,
- 35 as being necessary to take responsibility for managing the

- 1 well-being of the patient with respect to the medical use of
- 2 cannabidiol pursuant to the provisions of this chapter.
- 3 Sec. 2. Section 124D.3, Code 2016, is amended to read as 4 follows:
- 5 124D.3 Neurologist Health care practitioner recommendation
- 6 medical use of cannabidiol.
- 7 A neurologist health care practitioner who has examined
- 8 and treated a patient suffering from intractable epilepsy a
- 9 debilitating medical condition may provide but has no duty to
- 10 provide a written recommendation for the patient's medical use
- 11 of cannabidiol to treat or alleviate symptoms of intractable
- 12 epilepsy the debilitating medical condition
- 13 if no other satisfactory alternative treatment options exist
- 14 for the patient and all of the following conditions apply:
- 15 l. The patient is a permanent resident of this state.
- 16 2. A neurologist health care practitioner has treated
- 17 the patient for intractable epilepsy a debilitating medical
- 18 condition for at least six months. For purposes of this
- 19 treatment period, and notwithstanding section 124D.2,
- 20 subsection 4, treatment provided by a neurologist health care
- 21 practitioner may include treatment by an out-of-state licensed
- 22 neurologist health care practitioner in good standing.
- 23 3. The neurologist health care practitioner has tried
- 24 alternative treatment options that have not alleviated the
- 25 patient's symptoms.
- 26 4. The neurologist health care practitioner determines
- 27 the risks of recommending the medical use of cannabidiol are
- 28 reasonable in light of the potential benefit for the patient.
- 29 5. The neurologist health care practitioner maintains a
- 30 patient treatment plan.
- 31 Sec. 3. Section 124D.4, subsection 1, paragraph c, Code
- 32 2016, is amended to read as follows:
- 33  $\,$  c . Requests the patient's  $rac{\mathsf{neurologist}}{\mathsf{nealth}}$  health care
- 34 practitioner to submit a written recommendation to the
- 35 department signed by the neurologist health care practitioner

- 1 that the patient may benefit from the medical use of
- 2 cannabidiol pursuant to section 124D.3.
- 3 Sec. 4. Section 124D.4, subsection 1, paragraph d,
- 4 subparagraph (3), Code 2016, is amended to read as follows:
- 5 (3) Full name, address, and telephone number of the
- 6 patient's neurologist health care practitioner.
- 7 Sec. 5. Section 124D.4, subsection 1, Code 2016, is amended
- 8 by adding the following new paragraph:
- 9 NEW PARAGRAPH. e. Submits a cannabidiol registration card
- 10 fee of one hundred dollars to the department. If the patient
- 11 attests to receiving social security disability benefits,
- 12 supplemental security insurance benefits, or being enrolled in
- 13 the medical assistance program, the fee shall be twenty-five
- 14 dollars.
- 15 Sec. 6. Section 124D.4, subsection 3, paragraph b, Code
- 16 2016, is amended to read as follows:
- 17 b. Requests a patient's neurologist health care practitioner
- 18 to submit a written recommendation to the department signed by
- 19 the neurologist health care practitioner that a patient in the
- 20 primary caregiver's care may benefit from the medical use of
- 21 cannabidiol pursuant to section 124D.3.
- Sec. 7. Section 124D.4, subsection 3, paragraph c,
- 23 subparagraph (4), Code 2016, is amended to read as follows:
- 24 (4) Full name, address, and telephone number of the
- 25 patient's neurologist health care practitioner.
- Sec. 8. Section 124D.5, subsection 1, paragraph b,
- 27 subparagraph (1), Code 2016, is amended by adding the following
- 28 new subparagraph division:
- 29 NEW SUBPARAGRAPH DIVISION. (c) To authorized employees of
- 30 a medical cannabidiol manufacturer, but only for the purpose
- 31 of verifying that a person is lawfully in possession of a
- 32 cannabidiol registration card issued pursuant to this chapter.
- 33 Sec. 9. Section 124D.5, subsection 2, Code 2016, is amended
- 34 by striking the subsection and inserting in lieu thereof the
- 35 following:

- 2. The department shall adopt rules pursuant to chapter
- 2 17A to administer this chapter which shall include but not be
- 3 limited to rules to do all of the following:
- 4 a. Govern the manner in which the department shall consider
- 5 applications for new and renewal cannabidiol registration
- 6 cards.
- 7 b. Establish requirements for the suspension and revocation
- 8 of a cannabidiol registration card and a medical cannabidiol
- 9 manufacturer license.
- 10 c. Establish requirements for the licensure of medical
- 11 cannabidiol manufacturers and set forth procedures for medical
- 12 cannabidiol manufacturers to obtain licenses.
- d. Develop a dispensing system for medical cannabidiol
- 14 manufacturers to dispense cannabidiol within this state that
- 15 provides for all of the following:
- 16 (1) Medical cannabidiol manufacturers within this state
- 17 housed on secured grounds.
- 18 (2) The dispensing of cannabidiol to patients and their
- 19 primary caregivers in person to occur at medical cannabidiol
- 20 manufacturer locations designated by the department.
- 21 e. Establish and collect annual fees from medical
- 22 cannabidiol manufacturers to cover the costs associated with
- 23 regulating and inspecting medical cannabidiol manufacturers.
- 24 f. Specify and implement procedures that address public
- 25 safety including security procedures and product quality
- 26 including measures to ensure contaminant-free cultivation of
- 27 cannabidiol, safety, and appropriate labeling.
- 28 q. Establish and implement a real-time, statewide
- 29 cannabidiol registry management sale tracking system that
- 30 is available to medical cannabidiol manufacturers on a
- 31 twenty-four-hour-day, seven-day-a-week basis for the purpose
- 32 of verifying that a person is lawfully in possession of
- 33 a cannabidiol registration card issued pursuant to this
- 34 chapter and for tracking the date of the sale and quantity of
- 35 cannabidiol purchased by a patient or a primary caregiver.

- 1 h. Establish and implement a cannabidiol inventory and
- 2 delivery tracking system to track cannabidiol from production
- 3 by a medical cannabidiol manufacturer through dispensing by a
- 4 medical cannabidiol manufacturer.
- 5 Sec. 10. Section 124D.6, subsections 1 and 2, Code 2016, are
- 6 amended to read as follows:
- 7 l. a. A recommendation for the possession or use of
- 8 cannabidiol as authorized by this chapter shall be provided
- 9 exclusively by a neurologist health care practitioner for a
- 10 patient who has been diagnosed with intractable epilepsy a
- 11 debilitating medical condition.
- 12 b. Cannabidiol provided exclusively pursuant to the
- 13 recommendation of a neurologist shall be obtained from an
- 14 out-of-state source and health care practitioner shall only be
- 15 recommended for oral or transdermal administration.
- 16 c. A neurologist health care practitioner shall be the sole
- 17 authorized recommender as part of the treatment plan by the
- 18 neurologist health care practitioner of a patient diagnosed
- 19 with intractable epilepsy a debilitating medical condition.
- 20 A neurologist health care practitioner shall have the sole
- 21 authority to recommend the use or amount of cannabidiol,
- 22 if any, in the treatment plan of a patient diagnosed with
- 23 intractable epilepsy a debilitating medical condition.
- 24 2. A neurologist health care practitioner, including
- 25 any authorized agent thereof, shall not be subject to
- 26 prosecution for the unlawful recommendation, possession, or
- 27 administration of marijuana under the laws of this state for
- 28 activities arising directly out of or directly related to
- 29 the recommendation or use of cannabidiol in the treatment of
- 30 a patient diagnosed with intractable epilepsy a debilitating
- 31 medical condition.
- 32 Sec. 11. Section 124D.6, Code 2016, is amended by adding the
- 33 following new subsection:
- 34 NEW SUBSECTION. 2A. A medical cannabidiol manufacturer,
- 35 including any authorized agent or employee thereof, shall

- 1 not be subject to prosecution for manufacturing, possessing,
- 2 cultivating, harvesting, packaging, processing, transporting,
- 3 supplying, or dispensing cannabidiol pursuant to this chapter.
- Sec. 12. Section 124D.6, subsection 3, paragraphs a and b,
- 5 Code 2016, are amended to read as follows:
- 6 a. In a prosecution for the unlawful possession of marijuana
- 7 under the laws of this state, including but not limited to
- 8 chapters 124 and 453B, it is an affirmative and complete
- 9 defense to the prosecution that the patient has been diagnosed
- 10 with intractable epilepsy a debilitating medical condition,
- 11 used or possessed cannabidiol pursuant to a recommendation by a
- 12 neurologist health care practitioner as authorized under this
- 13 chapter, and, for a patient eighteen years of age or older, is
- 14 in possession of a valid cannabidiol registration card.
- 15 b. In a prosecution for the unlawful possession of
- 16 marijuana under the laws of this state, including but not
- 17 limited to chapters 124 and 453B, it is an affirmative and
- 18 complete defense to the prosecution that the person possessed
- 19 cannabidiol because the person is a primary caregiver of a
- 20 patient who has been diagnosed with intractable epilepsy a
- 21 debilitating medical condition and is in possession of a
- 22 valid cannabidiol registration card, and where the primary
- 23 caregiver's possession of the cannabidiol is on behalf of the
- 24 patient and for the patient's use only as authorized under this
- 25 chapter.
- 26 Sec. 13. NEW SECTION. 124D.9 Medical cannabidiol
- 27 manufacturer licensure.
- 28 1. The department shall license two medical cannabidiol
- 29 manufacturers by December 1, 2016, to manufacture and dispense
- 30 cannabidiol within this state consistent with the provisions
- 31 of this chapter. The department shall relicense the existing
- 32 medical cannabidiol manufacturers by December 1 of each year.
- 33 2. As a condition for licensure, a medical cannabidiol
- 34 manufacturer must agree to begin supplying and dispensing
- 35 cannabidiol to patients in this state by July 1, 2017.

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- 3. The department shall consider the following factors
- 2 in determining whether to license a medical cannabidiol
- 3 manufacturer:
- 4 a. The technical expertise of the medical cannabidiol
- 5 manufacturer in cannabidiol.
- 6 b. The qualifications of the medical cannabidiol
- 7 manufacturer's employees.
- 8 c. The long-term financial stability of the medical
- 9 cannabidiol manufacturer.
- 10 d. The ability to provide appropriate security measures on
- 11 the premises of the medical cannabidiol manufacturer.
- 12 e. The medical cannabidiol manufacturer's projection of
- 13 and ongoing assessment of fees on patients with debilitating
- 14 medical conditions.
- 15 4. The department shall require each medical cannabidiol
- 16 manufacturer to contract with the state hygienic laboratory at
- 17 the university of Iowa in Iowa City to test the cannabidiol
- 18 produced by the medical cannabidiol manufacturer as to
- 19 content, contamination, and consistency. The department shall
- 20 require that the laboratory report testing results to the
- 21 medical cannabidiol manufacturer in a manner determined by the
- 22 department pursuant to rule.
- 23 5. Each entity submitting an application for licensure as
- 24 a medical cannabidiol manufacturer shall pay a nonrefundable
- 25 application fee of ten thousand dollars to the department.
- 26 Sec. 14. NEW SECTION. 124D.10 Medical cannabidiol
- 27 manufacturers.
- 28 1. A medical cannabidiol manufacturer shall pay the cost of
- 29 all laboratory testing.
- 30 2. The operating documents of a medical cannabidiol
- 31 manufacturer shall include all of the following:
- 32 a. Procedures for the oversight of the medical cannabidiol
- 33 manufacturer and procedures to ensure accurate recordkeeping.
- 34 b. Procedures for the implementation of appropriate security
- 35 measures to deter and prevent the theft of cannabidiol and

- 1 unauthorized entrance into areas containing cannabidiol.
- 2 3. A medical cannabidiol manufacturer shall implement
- 3 security requirements, including requirements for protection
- 4 of each location by a fully operational security alarm system,
- 5 facility access controls, perimeter intrusion detection
- 6 systems, and a personnel identification system.
- A medical cannabidiol manufacturer shall not share
- 8 office space with, refer patients to, or have any financial
- 9 relationship with a health care practitioner.
- 10 5. A medical cannabidiol manufacturer shall not permit any
- 11 person to consume cannabidiol on the property of the medical
- 12 cannabidiol manufacturer.
- 13 6. A medical cannabidiol manufacturer is subject to
- 14 reasonable inspection by the department.
- 15 7. A medical cannabidiol manufacturer shall not employ a
- 16 person who is under twenty-one years of age or who has been
- 17 convicted of a disqualifying felony offense. An employee
- 18 of a medical cannabidiol manufacturer shall be subject to a
- 19 background investigation conducted by the division of criminal
- 20 investigation of the department of public safety and a national
- 21 criminal history background check.
- 22 8. A medical cannabidiol manufacturer shall comply with
- 23 reasonable restrictions set by the department relating to
- 24 signage, marketing, display, and advertising of cannabidiol.
- 9. a. All manufacturing, cultivating, harvesting,
- 26 packaging, and processing of cannabidiol shall take place in an
- 27 enclosed, locked facility at a physical address provided to the
- 28 department during the licensure process.
- 29 b. A medical cannabidiol manufacturer shall manufacture
- 30 a reliable and ongoing supply of cannabidiol to treat every
- 31 debilitating medical condition listed in this chapter.
- 32 c. A medical cannabidiol manufacturer shall not, within
- 33 a thirty-day period, dispense more than thirty-two ounces of
- 34 cannabidiol to a patient or a primary caregiver.
- 35 10. A medical cannabidiol manufacturer shall pay an

- 1 annual fee determined by the department equal to the cost of
- 2 regulating and inspecting the medical cannabidiol manufacturer
- 3 during that year.
- 4 Sec. 15. NEW SECTION. 124D.11 Fees.
- 5 Cannabidiol registration card fees and medical cannabidiol
- 6 manufacturer application and annual fees collected by the
- 7 department pursuant to this chapter shall be retained by
- 8 the department, shall be considered repayment receipts as
- 9 defined in section 8.2, and shall be used for the purpose of
- 10 regulating medical cannabidiol manufacturers and for other
- 11 expenses necessary for the administration of this chapter.
- 12 Notwithstanding section 8.33, moneys that remain unencumbered
- 13 or unobligated at the end of the fiscal year shall not revert
- 14 to the general fund of the state.
- 15 Sec. 16. <u>NEW SECTION</u>. **124D.12** Use of cannabidiol smoking 16 and vaping prohibited.
- 17 A patient shall not consume cannabidiol possessed or used as
- 18 authorized by this chapter by smoking or vaping cannabidiol.
- 19 Sec. 17. NEW SECTION. 124D.13 Penalties.
- A person who knowingly or intentionally possesses or uses
- 21 cannabidiol in violation of the requirements of this chapter is
- 22 subject to the penalties provided under chapters 124 and 453B.
- 23 2. A medical cannabidiol manufacturer shall be assessed
- 24 a civil penalty of up to one thousand dollars per violation
- 25 for any violation of this chapter in addition to any other
- 26 applicable penalties.
- 27 Sec. 18. REPEAL. Sections 124D.7 and 124D.8, Code 2016,
- 28 are repealed.
- 29 EXPLANATION
- The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.
- 32 This bill relates to the medical cannabidiol Act, makes
- 33 related modifications, and provides for civil and criminal
- 34 penalties and fees.
- 35 MEDICAL CANNABIDIOL ACT OVERVIEW. Iowa Code chapter

1 124D, the medical cannabidiol Act, currently allows an Iowa 2 licensed neurologist who has examined and treated a patient 3 suffering from intractable epilepsy to provide a written 4 recommendation for the patient's medical use of cannabidiol 5 to treat or alleviate symptoms of intractable epilepsy if 6 no other satisfactory alternative treatment options exist 7 and if certain conditions apply. A patient who receives a 8 written recommendation from the patient's neurologist or 9 the patient's primary caregiver is required to have a valid 10 cannabidiol registration card to use or possess cannabidiol 11 for medical purposes. The cannabidiol must be obtained from 12 an out-of-state source. The department of public health 13 is required to maintain a confidential file of the names 14 of each patient and primary caregiver to or for whom the 15 department issues a cannabidiol registration card and to keep 16 such information confidential except as otherwise allowed. 17 The medical cannabidiol Act provides affirmative defenses 18 to a neurologist, a patient, and a primary caregiver from 19 prosecution. A person who knowingly or intentionally possesses 20 or uses cannabidiol in violation of the medical cannabidiol 21 Act is subject to the penalties provided under Code chapters 22 124 (controlled substances) and 453B (excise taxes on unlawful 23 dealing in certain substances). DEBILITATING MEDICAL CONDITIONS - HEALTH CARE PRACTITIONER. 24 25 The bill amends the medical cannabidiol Act to include multiple 26 sclerosis and terminal cancer, in addition to intractable 27 epilepsy, as additional debilitating medical conditions for 28 which a patient may receive a written recommendation from a 29 health care practitioner for the patient's medical use of 30 cannabidiol. "Health care practitioner" is defined to mean any 31 Iowa licensed physician who provides specialty care for one or 32 more debilitating medical conditions. 33 CANNABIDIOL REGISTRATION CARD FEE. The bill requires a 34 patient to submit a cannabidiol registration card fee of \$100

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35 or \$25 to the department, depending on whether a patient is the

- 1 recipient of certain public assistance.
- 2 CONFIDENTIALITY. The bill provides that confidential
- 3 patient and primary caregiver cannabidiol registration card
- 4 information maintained by the department may be disclosed to
- 5 authorized employees of a medical cannabidiol manufacturer
- 6 under certain circumstances.
- 7 MEDICAL CANNABIDIOL MANUFACTURER LICENSURE. The bill
- 8 requires the department to license by December 1, 2016,
- 9 two medical cannabidiol manufacturers to manufacture and
- 10 dispense cannabidiol within this state. As a condition for
- 11 licensure, a medical cannabidiol manufacturer must agree to
- 12 begin supplying and dispensing cannabidiol to patients in
- 13 this state by July 1, 2017. The department is directed to
- 14 consider several factors in determining whether to license a
- 15 medical cannabidiol manufacturer. Each medical cannabidiol
- 16 manufacturer is required to contract with the state hygienic
- 17 laboratory at the university of Iowa to test the cannabidiol
- 18 produced by the manufacturer and to report testing results to
- 19 the medical cannabidiol manufacturer, and is required to pay a
- 20 nonrefundable application fee of \$10,000.
- 21 MEDICAL CANNABIDIOL MANUFACTURER ADDITIONAL REQUIREMENTS.
- 22 The bill provides that certain requirements must be included in
- 23 the operating documents of a medical cannabidiol manufacturer.
- 24 A medical cannabidiol manufacturer is prohibited from engaging
- 25 in certain activities and is subject to reasonable inspection
- 26 and reasonable restrictions by the department.
- 27 A medical cannabidiol manufacturer is required to provide
- 28 a reliable and ongoing supply of cannabidiol to treat every
- 29 debilitating medical condition pursuant to the provisions of
- 30 the bill and shall manufacture, cultivate, harvest, package,
- 31 and process cannabidiol in an enclosed, locked facility at
- 32 a physical address provided to the department during the
- 33 licensure process.
- 34 FEES. Cannabidiol registration card fees and medical
- 35 cannabidiol manufacturer application and annual fees collected

- 1 by the department shall be retained by the department, and
- 2 shall be used for the purpose of regulating medical cannabidiol
- 3 manufacturers and for other expenses necessary for the
- 4 administration of the bill.
- 5 ADDITIONAL DEPARTMENT DUTIES RULES. The bill requires
- 6 the department to adopt rules relating to cannabidiol
- 7 registration cards and medical cannabidiol manufacturer
- 8 licenses, requirements for the licensure of medical cannabidiol
- 9 manufacturers, a dispensing system for medical cannabidiol
- 10 manufacturers to dispense cannabidiol within this state
- 11 that follows certain requirements, annual fees from medical
- 12 cannabidiol manufacturers, public safety procedures, and the
- 13 establishment and implementation of a statewide cannabidiol
- 14 registry management sale tracking system.
- 15 USE OF CANNABIDIOL SMOKING AND VAPING PROHIBITED. The
- 16 bill provides that a patient, including an out-of-state patient
- 17 who is in Iowa, shall not consume the cannabidiol by smoking or
- 18 vaping the cannabidiol.
- 19 USE OF MEDICAL CANNABIDIOL AFFIRMATIVE DEFENSES.
- 20 The bill provides prosecution immunity for a health care
- 21 practitioner and a medical cannabidiol manufacturer
- 22 including any authorized agents or employees of the health
- 23 care practitioner or medical cannabidiol manufacturer, for
- 24 activities undertaken by the health care practitioner or
- 25 medical cannabidiol manufacturer, pursuant to the provisions
- 26 of the bill.
- 27 PENALTIES. The bill provides that a medical cannabidiol
- 28 manufacturer shall be assessed a civil penalty of up to \$1,000
- 29 per violation for any violation of the bill in addition to any
- 30 other applicable penalties.
- 31 REPEAL. The bill repeals Code sections 124D.7 (penalties)
- 32 and 124D.8 (repealing Code chapter 124D on July 1, 2017).